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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,902	05/15/2006	Jeffrey B. Kaplan	UMD-0111	8859

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,902	KAPLAN, JEFFREY B.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky, PhD	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-6,12-14 and 16-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 25, 2007 amending claims 20-22 and 26 has been entered.

Claims 1-34 are pending.

Election/Restrictions

Applicant's election with traverse of Group II, claims 7-11 and 15, SEQ ID NO:2, in the reply filed on June 25, 2007 is acknowledged. The traversal is on the ground(s) "that sufficient reasons and/or examples to justify a Restriction Requirement have not been provided. Applicants submit that it would not be unduly burdensome to examine the nucleic acids that encode the elected polypeptides. Applicants submit that it would not be unduly burdensome to search claims drawn to methods using the polypeptide of claims 8-9 or a composition of claim 11. A search of the polypeptide or composition will likely yield the same results as searching the methods themselves. Therefore, Applicants respectfully submit that the Examiner has not established an undue burden in examining Groups I to IV and VIII to X in the same application" (Remarks, page 6). This is not found persuasive because the examination of Groups I-IV and VIII-X would require additional search of patent and non-patent documents that are not required for Group II and would require additional considerations. Furthermore, Applicants are reminded that "**Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier"

(Office action mailed May 24, 2007, pages 6-7). Applicants further argue "that it would not be unduly burdensome to examine all of the polypeptides (A) to (E) (SEQ ID NOs: 2, 4, 6, 8, and 10). These sequences are all highly identical to one another. The sequences only differ by several amino acid residues from one another. For example, SEQ ID NO:2 only differs from SEQ ID NO:6 at amino acid residues 103 and 168 (See Figure 1). A search of one sequence would likely yield the other sequences. Therefore, Applicants respectfully submit that the Examiner has not established an undue burden in examining Groups (A) to (E) in the same application" (ibid). This is not found persuasive because the identity among sequences is in the range of 48.7%-30.5%. Each sequence should be searched separately. It is noted that Applicants do not state that the sequences are obvious over each other. Therefore, each sequence should be searched and considered separately.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 12-14 and 16-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups I, III-, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 25, 2007.

Claim Objections

Claim 7 is objected to as dependent from non-elected claims 1-4. In the interests of the compact prosecution claim 7 was construed as if it were properly written, i.e. included all limitations of claims 1-4.

Claims 7-11 and 15 are objected to because of the following informalities: a comma is not needed after "soluble".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7-11 and 15 are drawn to or depend from "an active fragment or variant of β-N-acetylglucosaminidase". "Active fragment" as "a portion of the amino acid sequence of SEQ ID NO:2, 4, 6, 8 or 10 with similarities to the consensus sequence of the family 20 glycosyl hydrolase" (page 13, lines 4-10). Neither the consensus sequence nor the active fragments of SEQ ID NO:2 are disclosed. However, a consensus sequence is usually a small sequence that dies not exhibit enzymatic properties. Therefore, the genus of active fragments of β-N-acetylglucosaminidase is defined by neither structure nor function. the specification defined "functionally equivalent variants" as "polypeptide sequences structurally different from the dispersin B protein, but having no significant

functional difference from the protein" (page 13, lines 11-15). Therefore, the genus of variants of β-N-acetylglucosaminidase" is defined by function only.

The specification discloses β-N-acetylglucosaminidase from *Actinobaciilus actinomycetemcomitans* strain CU1000N having the amino acid sequence of SEQ ID NO: 2 encoded by SEQ ID NO: 1 and β-N-acetylglucosaminidases from different sources having the amino acid sequence of SEQ ID NOs: 4, 6, 8 or 10 that are 48.7%-30.5% homologous to SEQ ID NO:2. The specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being β-N-acetylglucosaminidase and does not disclose the structure: function correlation common to all members of the genus. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 7-11 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for β-N-acetylglucosaminidase having the amino acid sequence of SEQ ID NO:2, fusion protein, a pharmaceutical composition and an antiseptic solution comprising thereof, does not reasonably provide enablement for β-N-acetylglucosaminidase comprising "an active fragment" or variant of β-N-acetylglucosaminidase having an undefined homology to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, *e.g.* multiple substitutions.

The specification does not support the broad scope of the claims which encompass active fragments or variants of β-N-acetylglucosaminidases having an

undefined structure because the specification does **not** establish: (A) regions of the protein structure which may be modified without affecting the β-N-acetylglucosaminidases enzymatic activity; (B) the general tolerance of β-N-acetylglucosaminidases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any of an enzyme residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Without sufficient guidance, beyond that provided, making β-N-acetylglucosaminidase comprising an active fragment of SEQ ID NO:2 or a variant thereof having no defined homology to SEQ ID NO;2 is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites "An isolated amino acid sequence". "Sequence" is not a chemical compound and cannot be isolated. Amending the claim to recite a protein, a polypeptide or β-N-acetylglucosaminidase, for example, would obviate this rejection.

Claim 10 recites 'the amino acid sequence of claim 8 or 9". There is no antecedent basis for this phrase as claims 8 and 9 are drawn to β-N-acetylglucosaminidase protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al.

Clarke et al (form PTO-1449 filed June 14, 2005, reference AA) teach β-N-acetylglucosaminidase having the amino acid that is 11.6% identical to SEQ ID NO:2 of the instant invention and a fusion protein comprising thereof (page 8806, 1st column; page 8811, Table 3). Therefore, it is comprising an active fragment thereof and is a variant thereof.

Claims 7-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham et al.

Graham et al (form PTO-1449 filed June 14, 2005, reference AB) teach β-N-acetylhexoaminidase having the amino acid that is 12.5% identical to SEQ ID NO:2 of the instant invention and a fusion protein comprising thereof (page 16823, 1st column; page 16824, 1st column). Therefore, it is comprising an active fragment thereof and is a variant thereof.

Claims 7-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Somerville et al.

Somerville et al (form PTO-1449 filed June 14, 2005, reference AD) teach β-N-acetylglucosaminidase having the amino acid that is 11.6% identical to SEQ ID NO:2 of the instant invention and a fusion protein comprising thereof (page 6751; page 6753). Therefore, it is comprising an active fragment thereof and is a variant thereof.

Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kaplan et al. J. Bacteriology (August 2003) Vol. 185, No. 16, pages 4693-4698 (form PTO-1449 filed June 14, 2005, reference AC). This is the work of the inventor's Group published after the effective filing date of this application of December 20, 2002. the disclosed sequence of 361 amino acids is 95.3% identical to SEQ ID NO:2, 100% identical to residues 21-381 of SEQ ID NO:2 (381 amino acids).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

July 6, 2007